



HARTFORD HOSPITAL

Great Doctors Are
Just The Beginning

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December 8, 1999

3600 '99 DEC 16 P2:06

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom This May Concern:

The proposed rule, Docket No. 98N-0581, relating to "Testing Human Blood Donors..." would create a number of significant problems for collecting facilities in its attempt to avoid a theoretical hazard. I would strongly recommend careful reconsideration of the proposed rule before instituting this poorly conceived solution to a theoretical problem for the following reasons:

1. AABB requires special labeling of autologous units in order to reduce the likelihood that these units will be inadvertently transfused to someone other than the donor for whom they are designated. Those units, which are not tested, or are optionally tested and found to be positive, could also have a prominent "BIOHAZARD" label attached or the "BIOHAZARD" designation could be incorporated into the presently required label. Prominent labeling, rather than testing, would avoid a cost that will add significantly to the cost of medical care.
2. Prohibiting the sale of salvaged plasma from autologous units would create less of an economic problem than would requiring the testing of all autologous units. It is also a more practical approach to this aspect of a conceived problem.
3. "Universal precautions" are, or should be, a way of life in health care facilities. This standard of practice has been instituted to protect personnel who are handling potentially infectious material such as blood and blood products. Requiring testing of autologous units will not prevent poor medical practice. Mandating testing will not prevent errors in collecting blood specimens or eliminate the administration of contaminated units of blood or blood products to the wrong person. If either or both of these should happen, units, which are in all likelihood not infectious for viruses for which testing is available, could then be quickly tested to determine infectivity.

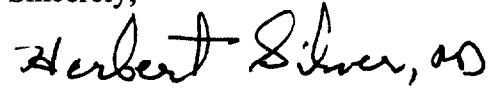
There is no evidence that the proposed rule referred to has been or will be of any benefit in terms of health care. Even on a theoretical basis as a means of preventing a disaster,

98N-0581

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the logic is faulty. In a facility such as mine, the cost of the mandatory testing proposed has been determined to be approximately \$100,000 while being of little or no proven benefit. Therefore, I would urge not only reconsideration but also abandonment of the entire proposal as written. Prominent labeling of autologous blood and blood products as BIOHAZARDOUS is a much more acceptable and practical approach to attaining the same outcome.

Sincerely,

A handwritten signature in black ink that reads "Herbert Silver, M.D." with a stylized flourish at the end.

Herbert Silver, M.D.

Director, Transfusion Medicine

HS:ss

pc: James T. Perkins, M.D.



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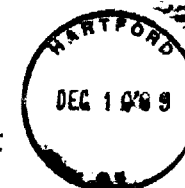
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